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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,215	12/08/2003	Liselotte Bjerre Knudsen	5367.230-US	3299
23650	7590	09/26/2005	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			MCKELVEY, TERRY ALAN	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/730,215

Applicant(s)

KNUDSEN ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,5 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5 and 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 08/922,200.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/1/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group VIII, claims 4-5 and 10-15 (species Gly2-GLP(1-33) in the reply filed on 10/22/04 is acknowledged. All of the non-elected claims have been canceled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of "promoting the treatment of intestinal cancer damage therapy in a patient" renders the claims vague and indefinite because it is unclear what is meant by treatment of therapy in this context. Does it mean treating the damage caused by intestinal cancer therapy? Alternatively, does it mean treating damage caused by intestinal cancer? Or, does it

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mean something else? The first definition was the one used to interpret the claims during examination.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Drucker et al (U.S. Patent No. 5,789,379).

Drucker et al teach GLP-2 analogs having the structure of SEQ ID NO:1 set forth in the reference which read on the structure of SEQ ID NO:1 in claim 4, wherein the second amino acid has been replaced with Gly to achieve resistance to DPP-IV digestion (column 6). This reference also teaches that small intestinal damage due to toxic or other chemotherapeutic agents can be treated by administering an effective amount of the GLP-2 analogs in a pharmaceutical composition to the patient (column 11), reading on "treatment of intestinal cancer damage therapy",

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because this phrase appears to mean treatment of damage caused by intestinal cancer therapy. Drucker et al teach that the GLP-2 pharmaceutical composition can be lyophilized and reconstituted in a suitable carrier prior to administration (column 10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

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U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-5 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drucker et al (U.S. Patent No. 5,789,379) in view of Kim et al (U.S. Patent No. 6,284,727 B1).

Drucker et al teach GLP-2 analogs having the structure of SEQ ID NO:1 set forth in the reference which read on the structure of SEQ ID NO:1 in claim 4, wherein the second amino acid has been replaced with Gly to achieve resistance to DPP-IV digestion (column 6). This reference also teaches that small intestinal damage due to toxic or other chemotherapeutic agents can be treated by administering the GLP-2 analogs in a pharmaceutical composition to the patient (column 11), reading on "treatment of intestinal cancer damage therapy", because this phrase appears to mean treatment of damage caused by intestinal cancer therapy. Drucker et al teach that the GLP-2 pharmaceutical composition can be lyophilized and reconstituted in a suitable carrier prior to administration (column 10). This reference also teaches that the GLP-2 pharmaceutical composition is optionally buffered and may be administered in a vehicle such as saline (which reads on an isotonic agent) (column 9).

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Drucker et al do not specifically teach use of a surfactant or preservative in the pharmaceutical composition comprising GLP-2 analog.

Kim et al teach that prolonged administration of GLP-1 and related peptides may be achieved by formulation as a solution in various water-soluble polymers, including polyethylene glycol (which is a surfactant), and may contain a suitable buffer, tonicity agent, and preservative (column 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to alter the GLP-2 pharmaceutical composition and administration method to treat intestinal damage as taught by Drucker et al by further including a surfactant such as PEG and a preservative as taught by Kim et al because Drucker et al teach that it is within the ordinary skill in the art to administer a pharmaceutical composition comprising GLP-2 to treat intestinal damage and Kim et al teach that it is within the ordinary skill in the art to include PEG and a preservative in pharmaceutical compositions comprising GLP-1 or related peptides (which reads on closely related GLP-2).

One would have been motivated to do so for the expected benefit of making the pharmaceutical composition comprising GLP-2 taught by Drucker et al achieve prolonged administration

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(which reads on increasing solubility and/or stability of the peptide) as taught by Kim et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### **Conclusion**

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.



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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

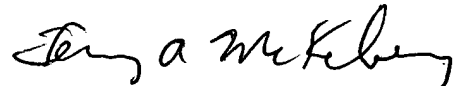
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should

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be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

September 15, 2005